K052412

SEP 16 2005

GE Healthcare

P.O. Box 414, W-400

Milwaukee, WI 53201 USA

1. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Healthcare
Tel. (262) 544-3894
Summary prepared: July 11, 2005

Identification of Product: Digital Fluoroscopic Imaging System
Classification Name: Fluoroscopic X-ray System
Manufacturer: GE Medical Systems SCS.
283, rue de la Minière
78530 Buc Cedex, France
Distributed by: GE Medical Systems, LLC, Milwaukee, WI

Marketed Devices: The GE Healthcare ***Innova 3D option*** for Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ} devices is substantially equivalent to the currently marketed software option Advantage 3D XR (K974715).

The GE Healthcare ***InnovaSpin*** **option** for Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ} devices is substantially equivalent to the currently marketed InnovaSpin option of the Vascular Angiographic system Innova 2100^{IQ} (2100-IQ) (K050489).

The GE Healthcare ***Innova 4100^{IQ}*** and ***Innova 3100^{IQ}*** devices are substantially equivalent to the currently marketed devices Innova 4100 device cleared under K033244 and Innova 3100 device cleared under K031637.

This opinion is based on the information contained in the comparison table and the product data sheets.

Device Description: The ***Innova 3D*** is offered as an option for Innova 4100 (already cleared under K033244), Innova 3100 (already cleared under

K031637), Innova 2100^{IQ} (2100-IQ) already cleared under K050489), Innova 4100^{IQ} and Innova 3100^{IQ}.

The ***InnovaSpin*** is offered as an option for Innova 4100 (already cleared under K033244), Innova 3100 (already cleared under K031637), Innova 4100^{IQ} and Innova 3100^{IQ}.

The Digital Fluoroscopic Imaging Systems Innova are designed to perform fluoroscopic x-ray examinations. The detector is comprised of amorphous silicon with a cesium iodine scintillator. The resulting digital image can be sent through a Fiber Channel link to an acquisition system then to network (in using DICOM) for applications such as post-processing, printing, viewing and archiving. Digital Fluoroscopic Imaging System consists of an a monoplane positioner, a vascular or cardiac table, an X-RAY system and a digital detector.

Materials: All construction and materials are compliant with UL 187 and IEC 60601-1 for the existing parts of the product and with UL 2601 and IEC 60601-1 for the new parts.

Design: The design is validated through Failures Modes Effects Analysis (FMEA) process, which allows managing the risks.

Energy Source: 480 VAC 50/60Hz.

Indications for Use: For Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ} with Innova 3D or InnovaSpin option:
The Innova systems are indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging procedures. They are also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures.
They are intended to replace fluoroscopic images obtained through image intensifier technology. Those devices are not intended for mammography applications.

Innova 3D is a software option which reconstructs 3D volumes from Rotational Fluoroscopy acquisition to assist the physician in diagnosis, surgical planning, interventional procedures and treatment follow-up.
It is not intended for mammography applications.

InnovaSpin is a software option that permits fast spin rotational angiography.
It is not intended for mammography applications.

Comparison with

The GE Healthcare ***Innova 3D option*** for Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ} devices is substantially equivalent to the currently marketed software option Advantage 3D XR (K974715).

The GE Healthcare ***InnovaSpin* option** for Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ} devices is substantially equivalent to the currently marketed InnovaSpin option of the Vascular Angiographic system Innova 2100^{IQ} (2100-IQ) (K050489).

The GE Healthcare ***Innova 4100^{IQ}*** and ***Innova 3100^{IQ}*** devices are substantially equivalent to the currently marketed devices Innova 4100 device cleared under K033244 and Innova 3100 device cleared under K031637.

The indications of use for the predicative devices are given below:

- *Advantage 3D XR indications for use*: The Advantage 3D XR is an X-ray imaging software option that offers the ability to construct a 3D model from images taken during a single DSA rotational angiography. The product is optimized for neuro-angiographic cases.

- *Innova 2100^{IQ} (2100-IQ) Indications for Use*: The Innova *2100^{IQ} (2100-IQ)* system is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography diagnostic and interventional procedures, and optionally, rotational angiography procedures. It is also indicated for generating fluoroscopic images of human anatomy for cardiology diagnostic and interventional procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. This device is not intended for mammography applications.

- *Innova 3100 indications for use*: The Digital Fluoroscopic Imaging System is indicated for use in diagnostic and interventional angiography procedures of human anatomy. It is intended to replace image intensifier fluoroscopic systems in all diagnostic or interventional angiography procedures. This device is not intended to mammography applications.

- *Innova 4100 indications for use*: The Digital Fluoroscopic Imaging System is indicated for use in generating fluoroscopic images of human anatomy for diagnostic and intervention angiography procedures. It is intended to replace fluoroscopic images obtained through the image intensifier technology. This device is not intended for mammography applications.

This opinion is based on the information contained in the comparison table and the product data sheets.

Summary of the Studies:

For the Innova 3D option:
Clinical data have been submitted been submitted in the Advantage 3D XR 510K (K954355).

For the InnovaSpin option:
Clinical data have been submitted in the LCV+ Version 2 system 510K (K993037), which indications for use is cardiac angiography.
Innova 2000 "Fast Spin Rotational Angiography" option has been submitted in 2002, cleared under K022322, without clinical data based on the fact that this mode of acquisition does not address different anatomies versus LCV+ Version 2 system (K993037).

Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ} and Innova 2100^{IQ} with InnovaSpin and Innova 3D options are considered substantially equivalent to the predicates in terms of image quality and diagnostic capabilities.
Therefore, previously submitted clinical data are applicable for this submission.

Conclusions:

GE Healthcare considers that the ***Innova 3D and Innova Spin*** options for Digital Fluoroscopic Imaging Systems Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ} and Innova 2100^{IQ} to be equivalent with the predicate devices. The potential hazards, related to the introduction of ***Innova 3D and InnovaSpin*** options are controlled by a risk management plan including:

- A hazard identification
- A risk evaluation
- A Software Development and Validation Process

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K052412 Third Party Organization: INTERTEK Testing Services

Third Party's Primary Reviewer(s): Hekin Hassen

ODE/OIVD Division: DRAID Branch/Team: Radiology

Section 2 – 510(k) Decision

Third party recommendation: SE V NSE ____ Other (specify): ____

ODE/OIVD final decision: SE V NSE ____ Other (specify): ____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	V		
b. Extent of pre-submission consultation with ODE/OIVD division	V		
c. Organization and format of review documentation	V		
d. Determination of 510(k) administrative completeness (screening review)	V		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	V		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences	V		
g. Rationale for conclusions and recommendation	V		
h. Use of guidance documents and standards	V		
i. Resolution of 510(k) deficiencies and FDA requests for additional information	V		
j. Scope of reviewer expertise and use of consulting reviewers	V		
k. Other (specify):			

Comments (explanation of ratings/issues): ____

Section 4 – ODE/OIVD Assessor Information

Assessed by: Rose Cosby Date: 9/15/05 Tel. No.: 594.1212

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2005

GE Healthcare
c/o Mr. Daniel W. Lehtonen
Responsible 3rd Party Official
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K052412
Trade/Device Name: Digital Fluoroscopic Imaging Systems – Innova 4100
Innova 4100[IQ], Innova 3100, Innova 3100 [IQ], Innova 2100 [IQ] with optional Innova 3D or optional InnovaSpin
Regulation Number: 21 CFR §892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 31, 2005
Received: September 2, 2005

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): K052412

Device Name: Digital Fluoroscopic Imaging Systems – Innova 4100, Innova 4100^{IQ}, Innova 3100, Innova 3100^{IQ}, Innova 2100^{IQ} with optional Innova 3D or optional InnovaSpin.

Indications for Use:

The Innova systems are indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging procedures. They are also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. They are intended to replace fluoroscopic images obtained through image intensifier technology. Those devices are not intended for mammography applications.

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InnovaSpin is a software option that permits fast spin rotational angiography. It is not intended for mammography applications.

Prescription Use	X	AND/OR	Over-The-Counter-Use	
(Part 21 CFR 801 Subpart D)			(Part 21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052412